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12 UNITED STATES DISTRICT COURT  
13 FOR THE CENTRAL DISTRICT OF CALIFORNIA  
14 EASTERN DIVISION

15 UNITED STATES OF AMERICA,

16 Plaintiff,

17 v.

18 CALIFORNIA STEM CELL  
19 TREATMENT CENTER, INC.,  
20 *et al.*

21 Defendants.  
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No. 5:18-CV-01005-JGB-KKx

**PLAINTIFF'S NOTICE OF RECENT  
DECISION**

Trial: May 4 – 13, 2021

Honorable Jesus G. Bernal  
United States District Judge

**NOTICE OF RECENT DECISION**

Plaintiff United States of America respectfully submits this Notice of Recent Decision in connection with *United States v. California Stem Cell Treatment Center, Inc.* The Court conducted a bench trial in this matter from May 4 through 13, 2021. The parties' Revised Proposed Findings of Fact and Conclusions of Law are due on June 8, 2021, and closing arguments are set for July 9, 2021.

The United States Court of Appeals for the Eleventh Circuit recently issued a decision in *United States v. U.S. Stem Cell Clinic*, No. 19-13276, --- F.3d ---, 2021 WL 2213288 (11<sup>th</sup> Cir. June 2, 2021) that directly addresses certain legal issues pending before this Court, including the interpretation of the "same surgical procedure" exception at 21 C.F.R. § 1271.15(b). A true and correct copy of the *US Stem Cell Clinic* decision is attached hereto as **Exhibit A**.

In *US Stem Cell Clinic*, the Eleventh Circuit held that the "same surgical procedure" exception "unambiguously does not apply to" defendants' adipose tissue-derived stromal vascular fraction (SVF) procedure "because the biological material implanted into the patient is not the same as that removed." *United States v. U.S. Stem Cell Clinic*, No. 19-13276, --- F.3d ---, 2021 WL 2213288 (11<sup>th</sup> Cir. June 2, 2021) at \*1, \*6. The Eleventh Circuit reasoned that "the plain text of the regulation suggests that 'such HCT/Ps' must be in the original form (rather than subjected to extensive processing)" whereas defendants' "stromal-vascular fraction solution is the product of an intensive cell isolation process involving enzymatic digestion that goes much farther than simple rinsing or sizing. By the time the stromal-vascular fraction is reinjected, it is no longer 'such HCT/P' as the adipose tissue removed from the patient." *Id.* at \*6.

The Eleventh Circuit's decision affirming the conclusion of the district court in that case<sup>1</sup> is the first court of appeals opinion to address this specific issue.

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<sup>1</sup> One of the defendants here, Elliot Lander, M.D., testified as an expert on behalf of the defendants in *US Stem Cell Clinic*, where he provided many of the same SVF-related opinions that both he and Lola Reid, Ph.D., provided in the instant case.

1 Dated: June 3, 2021

2 Respectfully Submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 3rd day of June 2021, I electronically filed a true and correct copy of the foregoing PLAINTIFF'S NOTICE OF RECENT DECISION through the Court's CM/ECF system, which will send a notice of electronic filing to the following counsel of record listed below:

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